REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action Summary, claims 1-16 and 23-46 were pending, with claims 23-40 being withdrawn from consideration. By the present response, claims 1, 15, 16, 41, 43 and 46 have been amended, claims 13-14 and 23-40 have been canceled, and claims 47-55 have been added. Thus, upon entry of the present response, claims 1-12, 15-16 and 41-55 are pending and await further consideration on the merits.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: paragraphs [0040], [0045] [0046], [0058], [0063], and [0102]-[0107]; and Figures 1A-2B.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 1-16 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement as set forth on page 2 of the Official Action.

It is alleged on page 2 of the Official Action, that the limitation, "said granules constituting a major fraction," is new matter. This assertion is respectfully traversed.

It is noted that the following portion of claim 1 was not objected to as constituting new matter, thus it is apparently recognized that the following portion of amended claim 1 satisfies the written description requirement:

a biocompatible polymer on at least a portion of said granules so as to form an implant mass comprising said granules and said biocompatible polymer, said biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass

As set forth above, the implant mass is formed by the granules and the biocompatible polymer. If 4% to about 20% of the total weight of the mass is the polymer component, i.e., a maximum of 1/5 of the implant mass is the polymer component, then the granules clearly form the major fraction of the implant mass. See also, e.g., paragraph [0063] of the original specification.

There is no requirement that original disclosure provide literal or explicit support for the claimed subject matter. See, e.g., MPEP §2163.

The grounds of rejection are clearly in error and should be withdrawn.

Claims 1-16 stand rejected under 35 U.S.C. §112, second paragraph, as being definite as set forth on page 2 of the Official Action.

By the present response, applicants have amended claim 1 in a manner which addresses the above-noted rejection. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 41, 43, 44 and 45 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,241,316 to Evans et al. (hereafter "*Evans et al.*") on the grounds set forth on page 3 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The present invention is directed to, *inter alia*, an implant mass and a composite matrix. The present invention provides certain benefits and advantages relative to compositions and articles of the prior art, including the ability to be quickly

shaped *in-situ* or *ex-situ* into a desired form or shape, and/or that can promote the in-growth or regeneration of bone tissue. A composite implant mass formed according to the principles of the present invention is set forth an amended claim 41. Amended claim 41 recites:

> *41. A composite implant mass comprising:*
> *a structural component, the structural component comprising a plurality of biocompatible synthetic non-polymeric granules, the granules being regularly-sized, regularly shaped, and/or spherical, and the granules having an equivalent diameter of about 100 µm to about 4,000 µm;*
> *a biocompatible polymer on at least a portion of the granules; and*
> *a plasticizer in an amount sufficient to condition at least a portion of the biocompatible polymer so that the implant mass is initially plastically deformable.*

A composite matrix formed according to the principles of the present invention as set forth an amended claim 43. Amended claim 43 recites:

> *43. A composite matrix comprising:*
> *a structural matrix, the structural matrix comprising a plurality of biocompatible synthetic non-polymeric granules bound together, at least in part, by a biocompatible polymer; and*
> *an open porous region comprising spaces or discontinuities between adjacent granules;*
> *wherein the structural matrix does not contain any bone particles.*

Evans et al. discloses an implant comprising collagen and/or other bioresorbable materials. It is alleged on pages 3 and 5 of the Official Action that *Evans et al.* discloses calcium phosphate or calcium sulfate particles having a size of about 100 µm. Column 8, lines 51-57 of *Evans et al.* is cited in support of the grounds of rejection. This portion of the *Evans et al.* disclosure reads as follows:

> *FIG. 23 depicts a 100x Scanning Electron Microscope image of a bone replacement material. A constituent of this implant is Kensey Nash P1076, a bovine-derived collagen material that is a combination of native collagen fibers and*

> *soluble collagen. Blended into the collagen is 25% by weight is a medical grade calcium sulfate, shown as the small cylindrical particles throughout the porous macrostructure.*

However, this portion of the *Evans et al.* disclosure does not disclose 100 μm particle size, or any other particle size for that matter. Thus, *Evans et al.* fails to anticipate at least this aspect of amended claim 41.

Amended claim 41 also requires "a biocompatible polymer on at least a portion of the granules." By contrast, *Evans et al.* fails to contain any disclosure whatsoever concerning the physical relationship between a biocompatible polymer and calcium phosphate or calcium sulfate particles. Thus, *Evans et al.* also fails to anticipate at least this aspect of claim 41.

As evident from the above, claim 43 requires, *inter alia*, "a structural matrix, the structural matrix comprising a plurality of biocompatible synthetic non-polymeric granules bound together. . . ." By contrast, as evident from the relied-upon portion of the *Evans et al.* disclosure, the calcium sulfate (or calcium phosphate) is not disclosed by *Evans et al.* as constituting a structural matrix, as required by claim 43. To the contrary, *Evans et al.* characterizes the calcium sulfate as being "dispersed throughout the porous macrostructure," thus indicating that the relatively minor fraction of calcium sulfate clearly does not form a structural matrix.

In addition, claim 43 also requires that the granules are bound together, at least in part, by the biocompatible polymer. By contrast, *Evans et al.* clearly fails to disclose that the calcium sulfate (or calcium phosphate) particles are bound together by a biocompatible polymer. Thus, *Evans et al.* fails to disclose at least this additional aspect of claim 43.

For at least the reasons noted above, *Evans et al.* clearly fails to anticipate either claim 41 or 43. The remaining rejected claims depend from either claim 41 or 43. Thus, these claims are also the distinguishable over *Evans et al.* for at least the reasons noted above. By the present response, claims 51-55 have been added. These claims depend from claims 41 or 43. Thus, newly presented claims 51-55 are also distinguishable over *Evans et al.* for at least the same reasons noted above.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1-15 and 41-46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,001,551 to Meredith (hereafter "*Meredith*") on the grounds set forth on page 4 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

A moldable implant composition formed according to the principles of the present invention as set forth in amended claim 1. Amended claimed 1 recites:

> *1. A moldable implant composition for use in repairing a bone defect in a living organism, comprising:*
> *a plurality of biocompatible synthetic non-polymeric granules, said granules constituting a major weight fraction of said implant composition and having an equivalent diameter of about 100 μm to about 4,000 μm;*
> *a biocompatible polymer coating at least a portion of said granules so as to form an implant mass comprising a plurality of distinct granules coated with said biocompatible polymer, said biocompatible polymer comprising about 4% to about 20% of the total weight of the implant mass; and*
> *a plasticizer in said implant mass in an amount sufficient to condition at least a portion of said biocompatible polymer so that said implant mass is initially plastically deformable into a desired shape and then hardenable upon removal of at least a portion of said plasticizer from said implant mass.*

It is alleged on page 4 of the Official Action that *Meredith* discloses a moldable implant composition including a plurality of biocompatible synthetic non-

polymeric granules "such as pulverized bone." First, applicants respectfuly traverse the assertion that pulverized bone is a synthetic material, which it is not.

As evident from the above, claim 1 also requires: "a biocompatible polymer coating at least a portion of said granules so as to form an implant mass comprising a plurality of distinct granules coated with said biocompatible polymer." *Meredith* appears to contain a broad disclosure that materials such as calcium phosphate and bioglass can be used filler materials (see, e.g. column 9, lines 3-13), however, *Meredith* fails to contain any disclosure whatsoever which would satisfy the above quoted limitation appearing in amended claim 1. In fact, *Meredith* fails to even suggest an implant mass having such characteristics. In fact, *Meredith* teaches away from the above quoted aspect of the implant mass of amended claim 1. *Meredith* teaches adding a particular material to mold, adding binder material into the mold, and applying a vacuum. *Meredith* discloses that: "[t]he binder acts as a matrix which binds the bone particles, thus providing coherency in a food environment and also improving the mechanical strength of the osteimplant." It is quite clear that *Meredith* fails to disclose or even suggest an implant mass formed by a plurality as distinct granules coated with a biocompatible polymer as required by amended claim 1. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Amended claim 41 recites an implant mass comprising granules that are: "regularly-sized, regularly-shaped, and/or spherical, and the granules having an equivalent diameter of about 100 μm to about 4000 μm." To the extent that the grounds of rejection are based upon an assertion that pulverized bone can constitute the granules recited in claim 41, this assertion is respectfully traversed. For instance, claim 41 also requires that the granules be "synthetic." By contrast,

pulverized bone is not a synthetic material. With respect to the broad disclosure of the inclusion of additional filler materials such as calcium phosphate and bioglass, *Meredith* contains no disclosure whatsoever concerning their morphology. In other words, *Meredith* clearly fails to disclose, or suggest, the above-quoted characteristics of the granules required by amended claim 41. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Amended claim 43 is directed to a composite matrix which is characterized by, *inter alia*, "the structural matrix does not contain any bone particles." By contrast, every embodiment disclosed by *Meredith* includes ground bone material. Thus, not only does *Meredith* fail to disclose at least this aspect of claim 43, it leads one of ordinary skill in the art away from the claimed composite matrix. Reconsideration and withdrawal of the rejection is respectfully requested.

The remaining claims depend from either claims 1, 41 or 43. Thus, these claims are also distinguishable over the applied prior art for the same reasons noted above. In addition, newly presented claims 47-55 depend from either claims 41 or 43. Thus, these newly presented claims are also distinguishable over the applied prior art for at least the same reasons as noted above.

Claims 1-16, 42 and 46 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Evans et al.* on the grounds set forth on page 4 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

It is alleged in the grounds for rejection that *Evans et al.* discloses all elements of the claimed invention except for the claimed weight percentage of the biocompatible polymer (i.e., 4% to about 20% by weight). This assertion is respectfully traversed.

Claim 1 requires, *inter alia*, biocompatible synthetic and non-polymeric granules constituting a major weight fraction of the implant composition and having an equivalent diameter of about 100 μm to about 4000 μm. It is alleged that the disclosure in column 8 of *Evans et al.* of the presence of 25% by weight of calcium sulfate satisfies the requirements of claim 1. This assertion is respectfully traversed. As should be abundantly clear, 25% by weight does not constitute a major weight fraction of the implant composition. Additionally, as explained above, *Evans et al.* contains no disclosure whatsoever concerning the particle size of calcium sulfate (or calcium phosphate). Therefore, at least the above-mentioned aspects of amended claim 1 are not disclosed by *Evans et al.*, contrary to the assertions contained in the grounds of rejection.

Claim 1 also characterizes the implant mass as comprising a plurality of distinct synthetic non-polymeric granules coated with a biocompatible polymer. *Evans et al.* fails to disclose that the calcium sulfate (or calcium phosphate) forms a plurality of distinct granules coated with a biocompatible polymer, required by amended claim 1.

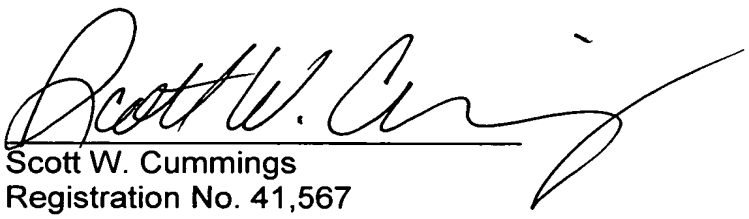
For at least reasons noted above, reconsideration and withdrawal of the rejection is respectfully requested. The remaining claims depend either directly or indirectly on claim 1. Thus, these claims are also distinguishable over *Evans et al.* for the same reasons noted above. In addition, newly presented claims 47-50 depend from claim 1. Thus, these newly presented claims are also distinctive over *Evans et al.* for at least the reasons noted above.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned be contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: March 18, 2009 By: 

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